Complex Thoracoabdominal Endovascular Repair should Preferentially be Performed Using Off the Shelf Devices Rather than Physician-Modified Endografts

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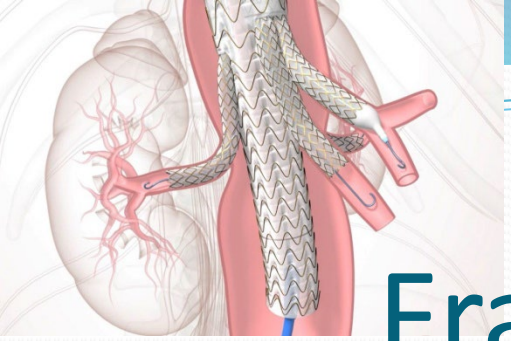
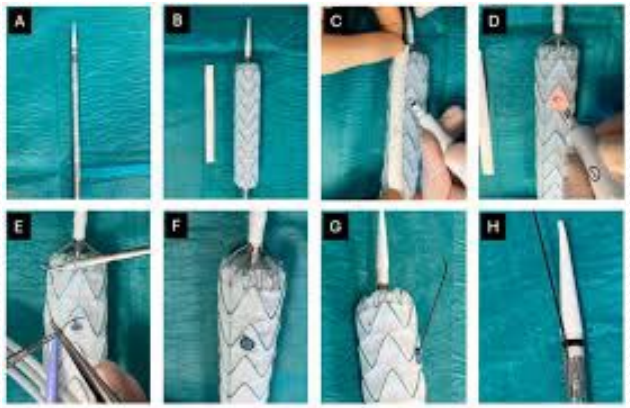
Disclosures

- Site PI: Gore, Penumbra, Shape
- SVS President Elect
- These are my own views



Frame the Debate

- TAMBE:
  - Off the shelf device
  - **Approved 2024** in US
- PMEG
  - Not FDA approved
  - **First described 2000** Tim Chuter
  - Over 2 decades experience in highly specialized centers
  - Initially developed to deal with patients with no other treatment options



Why go with something FDA approved?

- **Documented safety**/efficacy
- Rigorous quality control- for device failure
- **Liability issues**- manufacturer exempt if modified
- Potential for nonpayment
  - (CMS can choose not to reimburse if not under IDE)
- Standard outcomes
- IDE require a lot of time and $
  - Coordinator salary ,monitoring fees, secure database, clinical event committee, data safety monitoring board, report adverse events/deviations, annual progress reports
  - Subject to FDA inspection at any time

TAMBE: Current Results

- Multicenter ; 102 patients
- Freedom from
  - All cause mortality 94.2%
  - Re-intervention 78.7% for Type IV; 60.5% for PRAA
- 14.7% 1 target vessel occlusion at 1 year;
  - mostly left renal (and less than 5 mm) OR 3.94
  - 2 patients permanent Dialysis
- 22 re-intervention (15 pt)
  - 81% target vessel
  - 19% type II EL
- <u>No type I or III endoleak at 1 year</u>
- 6% increase aortic size; 23.8% shrink sac

Farber, M, et al JVS 2025

TAMBE Pivotal Trial Results vs PMEG at 1 institution

- 12 TAMBE (from trial); 56 PMEG
- Procedure time 247 min vs 189 < .001
- Technical success 100% TAMBE; 95% PMEG NS
- MAE-
  - TAMBE none;
  - PMEG 2% dialysis; 4% spinal cord ischemia
- Endoleaks:
  - TAMBE 50%- ALL type II
  - PMEG 41%: 11% type 1 or 3
- Vessel Instability: 10.4% TAMBE 6.9% PMEG (NS)
- Experienced center comparable results

JVS 2024; DiBartolomeo, A et al

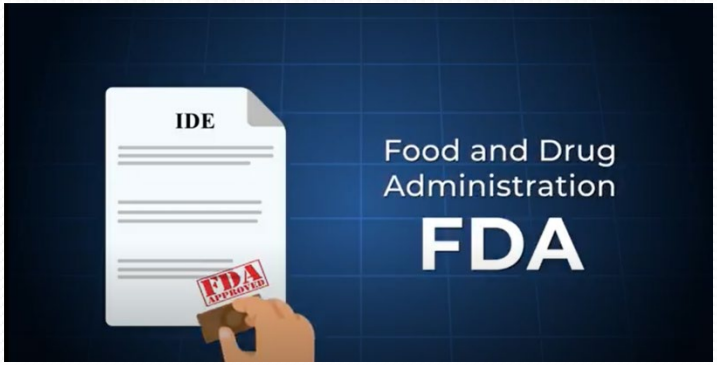
Multi-institutional Comparative Outcomes PMEG vs TAMBE

- 746 patients- prospective & retrospective data 2015-25
  - Mostly trial data for TAMBE
- 668 PMEG; 78 TAMBE
- Early mortality-
  - only in PMEG 3.9% p=.06
- MAE
  - 19% PMEG 17% TAMBE NS
- Freedom from target artery instability at 3 years
  - 77% PMEG; 64% TAMBE ; NS
  - Renal instability 89% PMEG, 73% TAMBE p = .02
- Freedom from Type I or III endoleak
  - 90% TAMBE 72% for PMEG (.02)

Tabiei, A, et al JVS, 2025

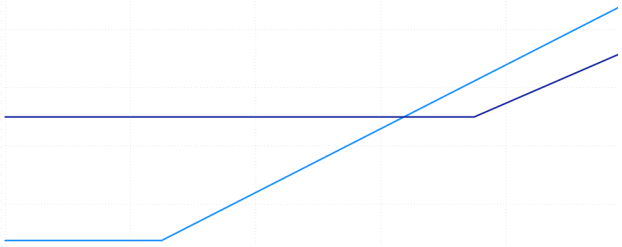
ISSUES with PMEG

- Requires centers of excellence
- Recommended ONLY for those with anatomy "unsuitable" for other repairs
- Safest to utilize if have IDE (investigational Device Exemption Protocol) with FDA
- Potential for fabric tears/deterioration over time due to device interactions



Issues with TAMBE

- Difference in target vessel instability
  - primarily - pararenal aneurysms, small renal arteries
- Risk wire wrapping for SMA and celiac
- Still in the learning curve



Updated Map - 2026

- Relatively unchanged from previously shared map
  - Certified and in-progress
- 450+ physicians attended training
- 2000+ cases
  - ~100 cases per month

PMEG Multicenter study Long term data

- International review (2007-22)-1274 patients from 19 centers;
  - 45.7% complex abdominal; 54.3% TAAA; 65.5% elective; 9.9% ruptured
  - 30 d mortality 5.8% (4.1% for elective)
  - Technical success 94% ; worse with accessory renal/visceral artery & prior aortic repair
- MAE 25.2% (23.1% for elective)
- Target vessel patency
  - 96.9%, 93.6% and 90.3% 1,3,5 years
- Overall freedom from re-intervention
  - 73.8%, 61.8% and 51.4% 1,3,5 years
- Freedom from branch occlusion or re-intervention
  - 89.4%, 78.5% and 72.1% at 1,3 and 5 years
- Endoleaks:
  - 26.9% developed or had persistent endoleak at follow-up
  - 14.7% type I or III
    Of type III 93% were branch related
- Freedom from endoleak from branch/fenestration
  - 86.6%, 79.4% and 73.9% 1,3,5 years
- Sac stability
  - 43.2% regression;42.5% stable
  - 14.3% enlarging

Circulation, Tsillmparis, N et al 2024

PMEG

- Decrease in MAE from before 2012 to after
  - 33.1% to 22% p<.001
- Over 3200 reported in VQI

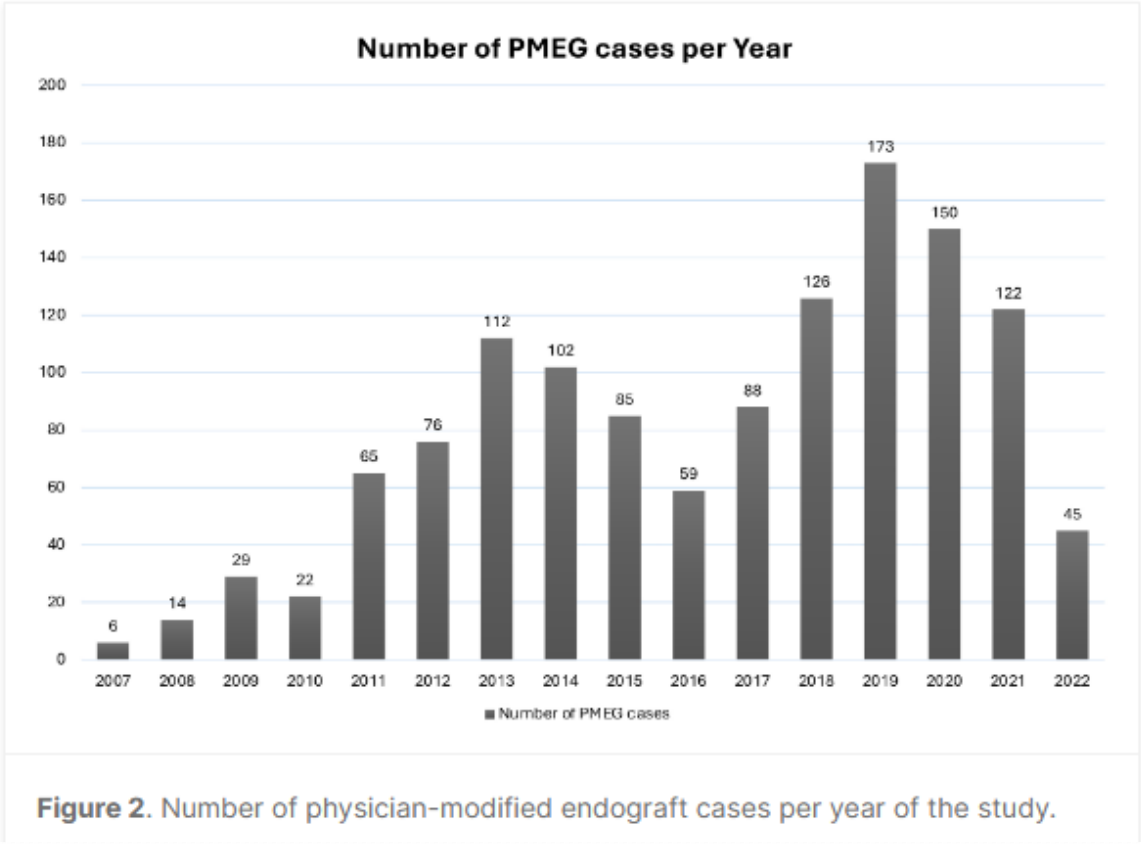


Figure 2. Number of physician-modified endograft cases per year of the study.

https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.123.068587

Conclusions:

- Both PMEG and TAMBE have
  - high technical success
  - Similar major adverse event rates
  - Good target vessel patency in both
  - Similar Re-intervention rates
- However:
  - Higher serious endoleak in PMEG (28% vs 10%)
  - More legal risk with PMEG
  - TAMBE is still early on learning curve and outcomes already excellent
  - PMEG data is only from highly specialized centers
- ***TAMBE should be the PREFERRED treatment for Complex Thoracoabdominal Aortic Aneurysms over PMEG***

QUESTIONS?

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Lets compare the 2 approaches

Issue	TAMBE	PMEG
FDA approved	Yes	No
	Off the shelf	customizable
Outcomes	3 year survival 100%	3 year survival 77%
Re-intervention rates	56% freedom 3 years	62% freedom 3 years
Branch instability	89% freedom 3 year 82.7% 5 year- renals	89% freedom 3 year 89.5% 5 year
OR issues	Longer procedure time	Shorter procedure time
Endoleaks	Lower Rate TI or III EL	Higher rate TI/TIII EL

Re-intervention after PMEG

- Common
- Re-intervention 29% (91/170 patient total)-
  - mean 1.8/patient
  - Most common- renal artery stent 26%
  - 24 -1 reintervention (48%); 36% - 2 and 16% multiple
- Indication for re-interventions
  - Endoleak 40%
    - 25% of endoleaks TIII, mostly IIIc
  - Target vessel intervention 13%
  - 3 patients reintervention for aotic aneurysm rupture
- The findings of recent studies on re-interventions and sac dynamics after PMEG led researchers to conclude that “vigilant” surveillance and a low threshold for further interventions are “crucial”

Tachida, A, et al, JVS 2023